Tab 6 – Course Bibliography

An * indicates a Required Reading. Reprints of all Required Readings are located behind the tab in this binder for the associated lecture. When available, reprints of Suggested Readings are also located behind the corresponding tab. **Bold** type indicates that reprints were unavailable at the time of production.

ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, Major Cardiovascular Events in Hypertensive Patients Randomized to Doxazosin vs Chlorthalidone: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attach Trial (ALLHAT), *JAMA*, April 19, 2000- Vol 283, No. 15

* Bailey, K., Inter-study differences: how should they influence the interpretation and analysis of results? *Stat Med*, 1987. 6: p. 351-358.

Barlow DH, Gorman JM, Shear MK, Woods SW: Cognitive-behavioral, imipramine, or their combination for panic disorder: a randomized controlled trial. *JAMA* 2000;283:2529-2536

Beecher, H.K., The powerful placebo, JAMA, 1955, 27: 1602-1606

Bellg, A.J, Borerelli, B, et al., Best Practices for Treatment Fidelity, In Press – *Health Psychology*.

- * Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. *Federal Register* Document 12065 (April 18, 1979), http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm
- * Cook, D.J., et al., Should unpublished data be included in meta-analysis? Current convictions and controversies. *Journal American Med Assn*, 1993. 269: p. 2749-2753.

Dickersin, K. and J.A. Berlin, Meta-analysis: state-of-the-science. *Epidemiologic Reviews*, 1992. 14: p. 154-176.

Entire Budget Period – Direct Costs Only Form, http://grants1.nih.gov/grants/funding/phs398/fp5.rtf

* Establishing Data and Safety Monitoring Boards (DSMBS) and Observational Study Monitoring Boards (OSMBS), *National Heart, Lung, and Blood Institute – National Institutes of Health*, (Revised October 30, 2001), http://www.nhlbi.nih.gov/funding/policies/dsmb_est.htm

Fleiss, J.L., The statistical basis of meta-analysis. *Statistical Methods in Medical Research*, 1993. 2(2): p. 121-146.

Follmann D, Proschan M, Biometrics 55, 732-737 (1999).

Frasure-Smith N, Prince R. Long-term follow-up of the Ischemic Heart Disease Life Stress Monitoring Program. *Psychosom Med* 1989;51:485-513.

Freedman, L, et al., Approaches to Monitoring the Results of Long-Term Disease Prevention Trias: Examples from the Women's Health Initiative, *Controlled Clinical Trials*, 17:509-525 (1996)

* Glasgow, R.E., Vogt, T.M., & Boles, S.M. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health*, 1999, 89: 1322-1327.

Goodman SN. Towards evidence-based medical statistics: 1: The P value fallacy. *Annals of Internal Medicine*, 1999, 130: 995-1004.

Gorman JM, Barlow DH, Ray S, Shear K, Woods S: Merging the cognitive behavioral and psychopharmacological paradigms in comparative studies: Controversies, issues, and some solutions. *Psychopharmacology Bulletin* 2001;35:111-124

- * HIPAA Privacy Rule and Its Impact on Research, Frequently Asked Questions
- * Hrobjartsson, A. and Gotzsche, P.C. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. *NEJM*, 2001, 344: 1594-1602

Initial Budget Period – Direct Costs Only Form, http://grants1.nih.gov/grants/funding/phs398/fp4.rtf

* ISIS-2 Collaborative Group (1988). The Lancet 2, 349-360.

Jobe, J. B., Smith, K., Tennstedt, S. L., Marsiske, M., Willis, S. L., Rebok, G. W., Morris, J. N., Helmers, K., Leveck, M. D., Kleinman, K. (2001). ACTIVE: A cognitive intervention trial to promote independence in older adults. *Controlled Clinical Trials*, 4, 453-479

* John, O.P., Benet-Martinez, V. Measurement: Reliability, Construct Validation and Scale Construction. In Reas HT, Judd, CM. (Eds.). *Handbook of Research Methods in Social and Personality Psychology*, pp.339-369. Cambridge, MA. Cambridge University Press, 2000.

Meinert CL, Tonascia S. Essential design features of a controlled clinical trial. In Meinert CL, Tonascia S. (eds). *Clinical Trials. Design, Conduct, and Analysis* pp. 65-70. New York, NY: Oxford University Press, 1986.

Meyer, G. J., Finn, S. E., Eyde, L. D., Kay, G. G., Moreland, K. L., Dies, R. R., Eisman, E. J., Kubiszyn, T. W., & Reed, G. M. (2001). Psychological testing and psychological assessment: A review of evidence and issues. *American Psychologist*, 56, 128-165.

Miklowitz, D.J., Clarkin, J.F. Balancing internal and external validity. *Prevention & Treatment*, 1999, 2 (http://www.journals.apa.org/prevention/volume2/toc-mar21-99.html)

NIH PHS398 Form.

http://grants1.nih.gov/grants/funding/phs398section 1.html#4 detailed

- * NIH Policy for Data and Safety Monitoring (June 10, 1998), *NIH Guide*, Notice 98-084, http://grants.nih.gov/grants/guide/notice-files/not98-084.html
- * NIMH Policy on Data and Safety Monitoring in Clinical Trials (September 2002), http://www.nimh.nih.gov/research/safetymonitoring.cfm

Oakes, M., The logic and role of meta-analysis in clinical research. *Statistical Methods in Medical Research*, 1993. 2(2): p. 147-160.

Persons, J.B. & Silberschatz, G. Are results of randomized controlled trials useful to psychotherapists? *Journal of Consulting and Clinical Psychology*, 1998, 66: 126-135.

- * Peto, R., Why do we need systematic overviews of randomized trials? Stat Med, 1987. 6: p. 233-240.
- * Pocock, S, (1982) Montioring Trial Progress, Chapter 10, Clinical Trials: A Practical Approach, (NY: John Wiley & Sons)

Powell LH. Unanswered questions in the Ischemic Heart Disease Life Stress Monitoring Program (Editorial). *Psychosom Med 1989*;51:479-484.

Pressel, S. et al., Operational Aspects of Terminating the Doxazosin Arm of the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), *Controlled Clinical Trials*, 22:29-41 (Feb. 2001)

* Price and Sikora (1995). *Treatment of Cancer*, 3rd edition, Chapman and Hall, London, section 52.4

Rothman KJ, Greenland S. Causation and Causal Inference. In Rothman KJ, Greenland S. (Eds.). *Modern Epidemiology*, 2nd *Edition*. pp. 7-28. Philadelphia, PA: Lippincott-Raven Publ., 1998.

Seligman MEP: Afterword—A Plea in PE Nathan and JM Gorman Treatments That Work, *New York: Oxford University Press*, 1998, pp. 568-573

* Slack, M.K. & Drugalis, J.R., Establishing the Internal and External Validity of Experimental Studies. *American Journal of Health-Systems Pharm.*, 2001, 58: 2173-2184.

Standards for Privacy of Individually Identifiable Health Information, *Federal Registar/* Vol. 67, No. 157/Wednesday, August 14, 2002/Rules and Regulations, 45 CFR Parts 160 and 164

* Turner, J.A., et al., The importance of placebo effects in pain treatment and research, *JAMA*, 1994, 271: 1609-1614.

Writing Committee for the ENRICHD Investigators. The Effects of Treating Depression and Low Perceived Social Support on Clinical Events After Myocardial Infarction: The Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) Randomized Trial. *JAMA*, 2003; 289:3106-3116.

Writing Group for the Women's Health Intiative Investigators, Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results from the Women's Health Initiative RCT, *JAMA*, July 17, 2002 – Vol 288, No. 3: 321-333

Zimmerman M, Mattia JI, Posternak MA: Are subjects in pharmacological treatment trials of depression representative of patients in routine clinical practice? *American Journal of Psychiatry* 2002;159:469-473